

REMARKS

Claims 1-7, 9, 16, 26-27, and 32-40 were pending in the application. By this amendment, claims 1, 6, 26, 32, 35, and 38-40 have been amended. No claims have been added or cancelled. Accordingly, claims 1-7, 9, 16, 26-27, and 32-40 remain pending.

The following remarks are in response to the grounds for rejection of claims set forth in the Office Action.

I. Claims Rejected Under 35 U.S.C. § 112

Claims 1-5 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite due to lack of antecedent basis for the term “the tissue fold” in the last line of claim 1. Claim 1 has been amended to reconcile the terminology used in the claim and to remove the basis for rejecting claims 1-5. Accordingly, Applicants request withdrawal of the rejections and allowance of the claims.

II. Claims Rejected Under 35 U.S.C. § 102

Claims 39 and 40 were rejected under 35 U.S.C. § 102(e) as being anticipated by Adams et al. (USP 6,736,828). Without acceding to the grounds for this rejection, Applicants respond as follows.

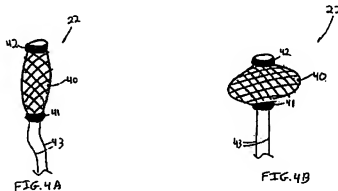
A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Claim 39 recites a method that includes the steps of moving a catheter into a patient, holding a tissue fold, extending a piercing element from the catheter through the tissue fold, moving a first anchor out from the piercing element, withdrawing the piercing element from the tissue fold, moving a second anchor out from the piercing element, and holding the tissue fold via a connection element connecting the first and second anchors. Claim 39 has been amended to recite: “with at least one of the first anchor and the second anchor comprising a sleeve of braided material and an eyelet for coupling the anchor to a connection element.”

Claim 40 recites a method that includes the steps of moving a catheter having a tissue grasper and a piercing element into a patient, holding a tissue fold, extending the piercing element from the catheter through the tissue fold, moving a first anchor out from the piercing element, withdrawing the piercing element from the tissue fold, moving a second anchor out from the piercing element, and holding the tissue fold via a connection element connecting the first and second anchors. Claim 40 has been amended to recite: “with at least one of the first anchor and the second anchor comprising a sleeve of braided material and an eyelet for coupling the anchor to a connection element.”

Support for the foregoing amendments to claims 39 and 40 is provided throughout the specification such as, for example, at paragraphs 0041-43 and at FIGS. 4A-B and 5A-C. For example, paragraph 0043 states the following in reference to the anchors illustrated in FIGS. 4A-B, which are reproduced below:

Anchor 22 may be made by thermo-forming two ends of a short length of braided sleeve to form proximal and distal bushings 41 and 42. Alternatively, separate bushings may be glued, over-molded, soldered or welded onto the ends of a length of braided sleeve. Suture(s) 43 may be attached to distal bushing 42 at a fixture point comprising, for example, one or more holes 46 formed in the distal bushing. Alternatively, the sutures may be attached using an eyelet, adhesive or other suitable fastener.



The Adams patent, on the other hand, describes a device and method of using the device that includes “various configurations of T-fasteners” illustrated in FIGS. 8-11 (see Adams, Col. 6, lines 25-41), a fastener with “inflatable balloons” at each end illustrated

in FIG. 12 (Adams, Col. 6, lines 42-61), a fastener with “deformable portions” near the proximal and distal ends illustrated in FIGS. 13a-13b (Adams, Col. 6, lines 62-67), a fastener that includes distal and proximal “stents” illustrated in FIGS. 16a-d (Adams, Col. 7, lines 49-59), and a two-part fastener including a “barbed tack” and a “mating washer” illustrated in FIG. 14 (Adams, Col. 7, lines 60-67). None of these fasteners is described in the Adams patent as comprising “a sleeve of braided material and an eyelet for coupling” the fastener to a suture, as recited in each of amended claims 39 and 40.

Accordingly, there can be no anticipation of either of claims 39 or 40 by the Adams patent. Applicants respectfully request withdrawal of these rejections and allowance of these claims.

III. Claims Rejected Under 35 U.S.C. § 103

Claims 1-2, 5-7, 9, 16, 26, and 32-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Adams patent in view of Saadat (USP 7,186,262). In addition, claim 3 was rejected as being unpatentable over the combination of Adams and Saadat in further view of Koike et al. (USP 6,056,760). Claim 4 was also rejected as being unpatentable over the combination of Adams and Saadat in further view of Laufer et al. (US Pub. No. 2004-0194790). Finally, claim 27 was rejected as being unpatentable over the combination of Adams and Saadat in further view of Gannoe et al. (USP 6,746,460). Without acceding to the grounds for these rejections, Applicants respond as follows.

To establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in

determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Claim 1 recites a method for delivering an anchor for use in a gastric reduction system that includes the steps of providing a delivery catheter having a needle with one or more anchors disposed within the needle, advancing the delivery catheter into the gastrointestinal lumen, engaging the stabilization device to a tissue wall, advancing the needle through the tissue wall, ejecting an anchor having an attached suture from a distal tip of the needle, withdrawing the needle, and translating a fastener over the suture. Claim 1 has been amended to recite "with at least one of the anchors comprising a sleeve of braided material and an eyelet for attaching the anchor to a suture."

Claim 6 recites a method that includes the steps of providing a delivery catheter including a piercing element with one or more anchors coupled to a suture disposed within the catheter, advancing the delivery catheter into the gastrointestinal lumen, engaging the stabilization device to a tissue wall, advancing the piercing element through a first tissue wall and a second tissue wall, ejecting first and second anchors from the piercing element, and advancing a fastener over the suture. Claim 6 has been amended to recite "with at least one of the anchors comprising a sleeve of braided material and an eyelet for coupling the anchor to the suture."

Claim 26 recites a method for creating a gastrointestinal tissue fold that includes the steps of providing a delivery catheter having a translatable needle and an anchor disposed within the needle and a suture coupled to the anchor, engaging and pulling a tissue wall of the gastrointestinal lumen to create a tissue fold, extending the needle through the tissue fold, ejecting the anchor from the needle, withdrawing the needle from the tissue fold whereby the suture is extended through the tissue fold, translating a fastener over the suture, and maintaining the tissue fold via the anchor and the suture. Claim 26 has been amended to recite "the anchor comprising a sleeve of braided material and an eyelet for coupling the anchor to a suture."

Claim 32 recites a method that includes the steps of moving a catheter into a patient, holding a tissue fold within the patient, extending a piercing element from the catheter through the tissue fold, moving a first anchor out from the piercing element on a

first side of the tissue fold, withdrawing the piercing element from the tissue fold, moving a second anchor out from the piercing element on a second side of the tissue fold, holding the tissue fold via a connection element connecting the first and second anchors, and advancing a fastener over the connection element to apply a tension force on said connection element. Claim 32 has been amended to recite: “with at least one of the first anchor and the second anchor comprising a sleeve of braided material and an eyelet for coupling the anchor to a connection element.”

Claim 35 recites a method of creating a tissue fold that includes the steps of moving a catheter to a surgical site of a patient, engaging and pulling a tissue wall to form a tissue fold, pushing a piercing element extending out of the catheter through the tissue fold, ejecting a first anchor from the piercing element, withdrawing the piercing element from the tissue fold, ejecting a second anchor from the piercing element, the second anchor being connected to the first anchor by a suture, and advancing a fastener over the suture to apply a tension force on said suture. Claim 35 has been amended to recite: “with at least one of the first anchor and the second anchor comprising a sleeve of braided material and an eyelet for coupling the anchor to the suture.”

Claim 38 recites a method that includes the steps of providing a system having a delivery catheter having a translatable needle and anchors disposed within the needle and a suture coupled to the anchors, engaging and pulling a tissue wall of the gastrointestinal tract of a patient to create a tissue fold, extending the needle through the tissue fold, placing an anchor on one side of the tissue fold, releasing the tissue fold, placing an anchor on the opposite side of the tissue fold, and advancing a fastener over the suture to apply a tension force on the suture. Claim 38 has been amended to recite: “with at least one of the anchors comprising a sleeve of braided material and an eyelet for coupling the anchor to the suture.”

Support for the foregoing amendments to claims 1, 6, 26, 32, 35, and 38 is provided throughout the specification such as, for example, at paragraphs 0041-43 and at FIGS. 4A-B and 5A-C, which are discussed in some detail in Section II above.

As also discussed in Section II above, none of the “fastener” devices described in the Adams patent constitutes “a sleeve of braided material” and none includes “an eyelet” for attaching or coupling a suture or other connection member. Instead, the Adams patent

describes “various configurations of T-fasteners” illustrated in FIGS. 8-11 (see Adams, Col. 6, lines 25-41), a fastener with “inflatable balloons” at each end illustrated in FIG. 12 (Adams, Col. 6, lines 42-61), a fastener with “deformable portions” near the proximal and distal ends illustrated in FIGS. 13a-13b (Adams, Col. 6, lines 62-67), a fastener that includes distal and proximal “stents” illustrated in FIGS. 16a-d (Adams, Col. 7, lines 49-59), and a two-part fastener including a “barbed tack” and a “mating washer” illustrated in FIG. 14 (Adams, Col. 7, lines 60-67). None of these components meets the limitations recited in the foregoing amended claims.

None of the other references relied upon in the Office Action to reject the foregoing claims corrects the deficiencies of the Adams patent. Specifically, neither the Saadat, Koike, Laufer, nor the Gannoe references describes a method that includes deploying an anchor “comprising a sleeve of braided material and an eyelet” for coupling or attaching the anchor to a suture or other connection element.

Accordingly, because none of the references cited in the Office Action discloses or suggests at least the foregoing limitations recited in claims 1, 6, 26, 32, 35, and 38, there can be no prima facie case of obviousness of those claims, or of the claims dependent therefrom. For these reasons, Applicants request withdrawal of the rejections of claims 1-7, 9, 16, 26, 27, and 32-38, and allowance of those claims.

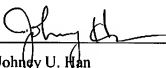
Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Similarly, unless explicitly stated, nothing contained or not contained in this paper should be construed as an assent to any of the Examiner’s stated grounds for rejecting the claims, including specifically the Examiner’s characterization of the teachings of the cited art and the Examiner’s contentions that any combinations of cited art would have been obvious. Rather, the present amendments to the claims and Remarks are an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02112**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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